

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

CHECKLIST FOR RESEARCH INVOLVING CHILDREN

Principal Investigator (Last, First): _____

Project Title: _____

1. Does the research involve greater than minimal risk? Yes ☐ No ☐

If “No,” skip to question #4.

2. If “Yes,” complete sections “A” or “B” or “C” below to determine under which category the research may be approvable.

A. There is the prospect of direct benefit for the individual subject.

- Is the risk justified by the anticipated benefits to the subjects? Yes ☐ No ☐
- Is the relation of anticipated benefits to the risk at least as favorable to the subjects as that presented by available alternative approaches? Yes ☐ No ☐

If all answers are “Yes”, skip to question 4.

B. The research holds no direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject’s disorder or condition.

- Does the risk represent a minor increase over Minimal risk? Yes ☐ No ☐
- Does the intervention or procedure present experiences to the subjects that are reasonably similar to those to be expected from their actual or expected medical, dental, psychological, social, or educational conditions? Yes ☐ No ☐
- Is the intervention or procedure likely to yield generalizable knowledge about the subjects’ disorder or condition that is of vital importance? Yes ☐ No ☐

C. The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children generally.

- Does the research present a reasonable opportunity To further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children? Yes ☐ No ☐
- Will the research be conducted in accordance with sound ethical principles? Yes ☐ No ☐

CPHS Use Only

Project # _____

Reviewer: _____

Date: _____

Rec: _____

To Rev: _____

From Rev: _____

Reviewer

Concurs:

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

3. Are any wards of the State to participate in the research?

Yes ☐ No ☐

☐ Yes ☐ No

If "Yes":

REQUIREMENT #1:

- Is the research related to their status as wards?

Yes ☐ No ☐

☐ Yes ☐ No

OR

- Is the research conducted in schools, camps, Hospitals, institutions, or similar settings in which the majority of children involved are not wards?

Yes ☐ No ☐

☐ Yes ☐ No

AND

REQUIREMENT #2:

- Has an advocate been appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis?

Yes ☐ No ☐

☐ Yes ☐ No

4. Parental Informed Consent and Child Assent

A. Does the research adequately provide for soliciting the permission of both of the child's parents or guardians?

Yes ☐ No ☐

☐ Yes ☐ No

If "No,":

- Will permission be sought from one parent only?

Yes ☐ No ☐

☐ Yes ☐ No

o If "Yes,":

- Is the research minimal risk or greater than minimal risk but presenting the prospect of direct benefit to the subjects?

Yes ☐ No ☐

☐ Yes ☐ No

B. Does the research provide for obtaining assent from Children 7-18 years of age?

Yes ☐ No ☐

☐ Yes ☐ No

If "No":

- Is a waiver of assent being requested?

Yes ☐ No ☐

☐ Yes ☐ No

• If "Yes,":

- Does the research protocol explain and provide the rationale for appropriate alternative mechanisms for protecting the children who participate?

Yes ☐ No ☐

☐ Yes ☐ No

Principal Investigator Signature: _____ Date: _____

CPHS Use Only

☐☐☐

Approved

Approval Deferred Pending Revisions

Refer to Full Committee

Comments:

Primary Reviewer Signature: _____ **Date:** _____

Checklist for Children--12-11-03